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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,370	06/19/2000	James M. White	1721-1	3966

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EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/596,370	WHITE, JAMES M.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This final rejection is in response to the amendment received on 06/20/2005

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 21-25, 29-31, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (U.S.P.N. 5,087,420) in view of Aubrey et al (U.S.P.N. 3,857,409) and further in view of Kern, Jr. et al (U.S.P.N. 6,000,418).

With respect to claims 21, 29, and 33, the Jackson reference discloses a method and a device for disposal of biological fluids (col.1, lines 57-60) such that the device includes a housing (11), a water flow inlet (20) and an outlet (22), a biological fluid line (col.3, lines 33-36) such that the water fluid line and the biological fluid line are mixed together (20, 24, and 26). The Jackson reference further teaches a disinfectant line (32) in communication with the water flow line (water inside 26) such that the disinfectant line

has an inlet outwardly of the housing (23). Further the disinfectant line (32 and water within 26) and the biological fluid line (24 and water within 26)) are connected with the water flow line. The Jackson reference further includes a disinfectant line (32) connected in valveless fluid communication (no valves are present on both the biological fluid line and the disinfectant line) with biological fluid line (24) at a connection point with the biological fluid line within the housing (36 and 11) between the water flow line (30) and an inlet of the biological fluid line (38 and 36) wherein the biological fluid line being substantially blood (col.1, lines 59-60). The disinfectant line and the biological fluid line are in communication within the housing (36 and 11). Furthermore, the disinfectant line (32) is in fluid communication with the water flow line (water inside 26). The Jackson reference goes on to disclose a method of disposing biological fluids (col.4, lines 51-68 and columns 5-6) including the following steps: connecting the biological fluid line in valveless relation to a disinfectant line (24 is connected to 32 through 26) at a connection point (32), connecting a water flow line to an outlet of the biological fluid line and the disinfectant line (30 is connected to the outlets of 38 and 32), mixing the biological fluid and the disinfectant together (mixed in 26), and discharging the water and the mixed biological fluid and disinfectant from water flow line (22). The biological fluid flow in fluid line and the disinfectant flow in the disinfectant line coincide (both 24 and 32 mix together in 26 and both occupy the same place in time) together. However, the Jackson reference fails to teach that solely the flow of water causes the simultaneous (i.e., coinciding in time) suction and mixing of both the disinfectant and the biological fluid lines (venturi means) and the housing contains no pumps. The Aubrey

reference housing includes no pumps (col. 7,lines 64-67 and col.8, lines 1-6), but there is no teaching that solely the flow of water causes the simultaneous suction and mixing of both the disinfectant and the biological fluid lines. The Kern reference discloses the concept that the flow of water causes the suction and mixing of different fluids (col.5, lines 17-23). For example, the flow of the diluent in channel (33) determines the suction action of the injectate in channel (39). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to delete the pump (37) of the Jackson reference and substitute the venturi effect of mixing of the Kern reference for the known and expected result of being able to mix fluids in the absence of any pumps to provide movement of the fluids to be mixed.

With respect to claim 22, the Jackson reference discloses a device having water flow inlet (20) means and outlet means (22) such that the inlet means is for passing water and the outlet means for releasing a mixture of the biological fluid and the water and the disinfectant (col.6, lines 41-45).

With respect to claim 23, the Jackson reference discloses a device that includes a water inlet (20) communicating with one end of water flow line (30a) and an outlet means (22) connected to water flow line (46) on an opposite end of water flow line such that outlet means for passing a flow of liquid to a sewer (col.6, lines 46-47).

With respect to claim 24, the Jackson reference device includes a pipe (39) communicating with the water flow line (30 such that both communicate with each other through 26), the disinfectant line (32) having a connection to the pipe (connection between 32 and 26) at a distance from the water flow line (30) and between an inlet of

the pipe (unlabeled inlet for 39) and water flow line (30) such that the biological fluid (38) mixing with the disinfectant (32) in pipe (39).

With respect to claim 25, the device of the Jackson reference places a valve (40) along the pipe (39) along the such that if for example the valve (40) is opened then the rate of the biological fluid is reduced since all the biological fluid is emptied from (26) to reservoir (27). However, the Jackson reference fails to place a valve between the inlet of the pipe and the connection to the disinfectant line. The device in the Kern reference includes a valve (unlabeled in figure 2 within the area A) connected to the pipe (unlabeled part of 26 between the valve and 22 within the area A) between the inlet of the pipe (unlabeled connection between the valve and the pipe in figure 2 within the area A) and connection to the injection tube 21. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the valve between inlet of the pipe and connection to the disinfectant in the Jackson apparatus since such a modification is a matter of choice of design of the artisan evidenced by the Kern reference.

With respect to claim 31, the Jackson reference teaches that the treated fluid is interconnected to a sewer (22 and col.6, lines 45-47).

With respect to claim 34, the Jackson reference discloses a method that includes connecting the disinfectant line (32) to the biological fluid line (24 through 26) between an inlet of the biological fluid line (36) and the outlet of the disinfectant line (outlet of 32).

With respect to claim 30, both the Jackson reference and the Aubrey reference fail to teach the use of venturi means; however, the Kern reference discloses the

concept of venturi means such that solely a water flow across openings of various different fluids creates a suction force (col.5, lines 17-23). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to delete the pump (37) of the Jackson reference and substitute the venturi effect of mixing of the Kern reference for the known and expected result of being able to mix fluids in the absence of any pumps to provide movement of the fluids to be mixed.

4. Claims 26-28, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (U.S.P.N. 5,087,420) in view of Aubrey et al (U.S.P.N. 3,857,409) and Kern, Jr. et al (U.S.P.N. 6,000,418) as applied to claims 21, 29 and 33 above and further in view of Griffiths (U.S.P.N. 5,914,047).

The Jackson reference discloses a pipe (39) in valveless communication with the biological fluid line (38) at a connection point (unlabeled connection between 26 and 39) within the housing (11); however, with respect to claims 26-28, 32 and 35, the Jackson, the Aubrey and the Kern references all fail to disclose containers for biological and disinfectant fluids such that the fluid lines are inserted into the containers, however; the Griffiths reference discloses the following: a suction line for insertion into a biological fluid container (70A), a biological fluid container (46A) having a top level (68), inserting an inlet of the biological fluid line into a container of biological fluid (col.7, lines 33-35), a disinfectant container (80) having a top level (82), and a suction line for insertion into a disinfectant fluid container (84). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and the device of the Jackson reference to include a biological fluid container and disinfectant

container as taught by the Griffiths reference since it functions as a container for untreated liquid waste (col.7, lines 31-32).

Response to Arguments

5. Applicant's arguments filed on 06/20/2005 have been fully considered but they are not persuasive.

On page 9 of the Remarks section, applicant argues that, "The disinfection line is not disclosed by reference numeral 32 of the Jackson patent. Reference numeral 32 is only an inlet channel for mixing the biological fluid line and the water flow line." The examiner disagrees. In col.5, lines 56-61, the Jackson reference teaches that the inlet for the disinfectant is through inlet 23, which is connected to disinfectant line, i.e., channel 32 through which the disinfectant flows to treat biological matter in reservoir 27. Clearly, the liquid disinfectant is independently flowing in line 32 in the Jackson reference.

On page 9 of the Remarks section, applicant argues that, "Figure 1 and 2 of the present invention show outlet 22 as analogous to this channel 32 of the Jackson patent element." The examiner disagrees since channel 32 is a structure through which disinfectant is flowing through inlet 23 as mentioned above. Again, see col.5, lines 56-61 and figure 1:23 and figure 6:32.

On page 10 of the Remarks section, applicant argues that, "There is no suggestion that the fluid pumps are eliminated. Only replenisher pumps are considered optional." The examiner disagrees. The Aubrey reference housing includes no pumps (col. 7, lines 64-67 and col.8, lines 1-6) regardless of the type of the pump. Further, a

replenisher pump is a fluid pump. The Aubrey reference is combined for the reason that the concept of not using pumps in the art of fluid mixing is known.

On page 10 of the Remarks section, applicant argues that, "The pump 37 of the Jackson patent being replaced by a venturi effect simply discloses the already known prior art, which is outlet 22 in figures 1 and 2 of the present invention." The examiner disagrees since the Kern reference discloses the concept that the flow of water causes the suction and mixing of different fluids (col.5, lines 17-23). For example, the flow of the diluent in channel (33) determines the suction action of the injectate in channel (39). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to delete the pump (37) of the Jackson reference and substitute the venturi effect of mixing of the Kern reference for the known and expected result of being able to mix fluids in the absence of any pumps to provide movement of the fluids to be mixed.

On page 10 of the Remarks section, applicant argues that, "It is most likely beyond reasonable interpretation to characterize the macerator 26 element of the Jackson patent as both the disinfectant line 32 and a water line 30." The examiner disagrees since in rejecting claim 24 on page 6 of the action dated 12/16/2004, the different elements of the claim were addressed as the following: a pipe (39), a water flow line (30), a disinfectant line (32) having a connection point to the pipe between (32 and 26) at a distance from the water flow line (30) and the biological fluid in line (38) is mixed with disinfectant in disinfectant line (32) in pipe (39). The macerator (26) is recited as a point of communication, for example, between the pipe (39) and the water

flow line (30) and not as both the disinfectant line and the water line as mentioned in the Remarks section.

On page 11 of the Remarks section, applicant argues that, "These limitations on the container connections are not disclosed or suggested by the combination with the Griffiths patent because the Griffiths patent teaches pumps 108 to create the flow of disinfectant." The applicant has amended claim 27 in the amendment received on 06/20/2005 and as a result the examiner has amended the rejection of the claim as shown above. The instant rejection of currently amended claim 27 stands as the following: the Jackson reference discloses a pipe (39) in valveless communication with the biological fluid line (38) at a connection point (unlabeled connection between 26 and 39) within the housing (11); however, with respect to claims 26-28, 32 and 35, the Jackson, the Aubrey and the Kern references all fail to disclose containers for biological and disinfectant fluids such that the fluid lines are inserted into the containers, however; the Griffiths reference discloses the following: a suction line for insertion into a biological fluid container (70A), a biological fluid container (46A) having a top level (68), inserting an inlet of the biological fluid line into a container of biological fluid (clo.7, lines 33-35), a disinfectant container (80) having a top level (82), and a suction line for insertion into a disinfectant fluid container (84). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and the device of the Jackson reference to include a biological fluid container as taught by the Griffiths reference since it functions as a container for untreated liquid waste (col.7, lines 31-32).

On page 11 of the Remarks section, applicant argues that, "These limitations on the container connections are not disclosed or suggested by the combination with the Griffiths patent because the Griffiths patent teaches pumps 108 to create the flow of disinfectant." The examiner disagrees since the Griffiths reference is combined to show that having a medical waste treatment device with a disinfectant and biological containers along with connections thereof is known and not for the use of pumps.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

7. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JOHN KIM can be reached on (571) 272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
08/23/2005

JOHN KIM
SUPERVISORY PATENT EXAMINER